

### **REMARKS**

Applicant's attorney wishes to express his appreciation to Examiner Gollamudi for her constructive comments during the telephonic interviews conducted June 4, 2004 and June 5, 2004. As suggested by the Examiner, claim 15, as well as claim 16 dependent thereon, have been amended recite that the composition used in the method for the treatment of nail infection comprises 0.1% to 25% of the active ingredient. In addition, claim 15, as well as claim 16 dependent thereon, have been amended to recite that the composition used in the method for the treatment of nails comprises at least one member selected from the group consisting of white mineral oil, petroleum jelly and paraffin wax. Claims 1 – 14 have been canceled, without prejudice, to expedite prosecution of this application. Each of the amendments to claims 15 and 16 is clearly supported by page 8, lines 5-6 and page 7, lines 2-3 of the original specification.

The present invention, as recited by claims 15 – 16, as amended, provides a unique means for treating onychomycosis consisting of a method for the topical treatment of nail infections. The method comprises applying to the infected nail a composition comprising at least one species selected from the group consisting of 2,2' -(alkyldioxy) bis-(alkyl-1,3,2-dioxaborinane) and 2,2'-oxybis(alkyl-1,3,2-dioxaborinane) and at least one member selected from the group consisting of white mineral oil, petroleum jelly and paraffin wax. More specifically, the composition comprises at least one member selected from the group consisting of 2,2' - (1-methyltrimethylene dioxy) bis - (4-methyl-1, 3, 2-dioxaborinane) and 2,2' - oxybis (4, 4, 6 - trimethyl-1, 3, 2-dioxaborinane) and at least one member selected from the group consisting of white mineral oil, petroleum jelly and paraffin wax. As described in detail by Examples 1-20 of

the original specification, the application of this composition effectively killed the most common pathogen causing onychomycosis, *Candida albicans*. Importantly it was determined by *in vivo* tests on five (5) volunteers that formulations of the invention achieve efficacy in the treatment of onychomycosis without skin irritation or noticeable side effects. See, in this respect, Examples 16-20 of the original specification.

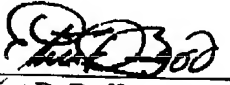
Secondary factors indicate the patentability of the present invention. There still remains a strong need in the industry for a nail formulation that can be applied topically in the treatment of nail fungus. The only effective currently marketed treatment for nail fungus is the oral intake of the prescription drug, Lamisil/terbinafine. In addition to the potential side effects from the oral intake of the anti-fungal prescription drug, many insurance plans do not cover the treatment of nail fungus with the oral prescription drug, Lamisil/terbinafine. If it would have been obvious to make a nail formulation that can be applied topically in the treatment of nail fungus there would likely be a marketed dioxaborinane composition for the topical treatment of nail fungus.

In order to emphasize the patentable distinctions of applicant's invention over the prior art, present claim 15, and claim 16 dependent thereon, have been amended to indicate a method for the treatment of nail infections comprising a composition including as active ingredient at least one member selected from the group consisting of 2,2' - (1-methyltrimethylene dioxy) bis - (4-methyl-1, 3, 2-dioxaborinane) and 2,2' - oxybis (4, 4, 6 - trimethyl-1, 3, 2-dioxaborinane), wherein the active ingredient is between 0.1 wt% and 25 wt% of the composition, and at least one member selected from the group consisting of white mineral oil, petroleum jelly and paraffin wax.

In light of the amendment to the claims and the remarks set forth above and discussed in detail during the Telephonic Interviews, it is submitted that the subject matter of present claims 15 - 16 patentable defines over the art applied and that the present application is in

allowable condition. Accordingly, entry of this amendment, reconsideration of the rejection of present claims 15 – 16 and their allowance are earnestly solicited.

Respectfully submitted,  
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